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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/047,434

10/25/2001

Rajendra Singh

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06/25/2004

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EXAMINER

CEPERLEY, MARY

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 06/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/047,434

Applicant(s)

SINGH ET AL.

Examiner

Mary (Molly) E. Ceperley

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 12-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/24/02, 6/04/02</u> . | 6) <input type="checkbox"/> Other: _____ |

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1) Claims 12-26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 19, 2004.

2) The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. See, for example, page 3 of the specification. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01 and 608.01(p).

3) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) In claim 1, it is unclear how "a protein mass tag (PMT) reagent", i.e. a single entity, can be "differentially" labeled with multiple "chemical substituents". The term "differentially" implies that more than one "protein mass tag (PMT) reagent" entity must be present in the composition.

b) In claim 1, it is unclear how the "protein mass tag" can be "differentially" labeled with only one "chemical substituent".

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c) The exact composition of the "protein mass tag (PMT) reagent" of claim 1 cannot be determined. The only requirement for the structure is that it contain "an amino acid reactive moiety that selectively reacts with certain protein functional groups" and that it be "differentially labeled". These two requirements are inadequate to chemically and functionally define the composition including its core structure. Additionally, which "certain protein functional groups" are intended is unclear. Claim 1, as written, is readable on any/all compound(s) which contain, for example, a single thiol group ("amino acid reactive moiety") and two different halogen atoms. In claim 2, it is unclear what is meant by the term "homologous organic substituents".

d) In claims 4 and 5, the term "said protein functional group is an amino acid side chain" is inconsistent with conventional nomenclature wherein a "functional group" may be present on an amino acid side chain but is not, itself, "an amino acid side chain". Clarification is required.

e) The Markush group definitions recited in claim 6 are not conventionally acceptable definitions of the term "protein functional groups". "Protein functional groups" are conventionally moieties such as thiols and maleimides present on the protein but are not conventionally entire "amino acids", "set of amino acids", "protein fragments", etc.

f) In claim 6, it is unclear what is meant by the terms "modified", "a set" and "digested".

g) It is unclear what the difference in meaning is between the terms "differentially" (claim 1) and "differently" (claim 8).

h) In claims 10 and 11, there is no antecedent basis for the term "protein reactive moieties".

i) It is unclear in claim 11 how the "protein reactive moiety reacts with *the side chain of arginine*" since the only reactive portion of the side chain is a guanidinium group.

6) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7) Claims 1-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Aebersold et al (U.S. 6,670,194).

Aebersold et al describe affinity labeled protein reactive reagents having an affinity label (A) covalently linked to a protein reactive group (PRG) through a linker group (L). The $-CH_2-$ groups of the linker (L) can be substituted with different hydrocarbyl, alkoxy or functional groups. See col. 4, line 1 – col. 5, line 60, especially col. 5, lines 4-12. Note that the compounds are not required to contain isotopes (see col. 5, lines 12-15: “one or more of the atoms in the linker *can* be substituted with a stable isotope”; col. 4, line 8: “the linker *may be* differentially isotopically labeled”), i.e. the corresponding compounds which do not contain isotope labels are described.

The compounds of Aebersold et al anticipate the “reagent” of instant claim 1 which requires *solely* “an amino reactive moiety” (corresponds to the PRG moiety of the Aebersold et al compound) and a “differential label” composed of “non-isotopic chemical substituent(s)” (readable on the differentially substituted $-CH_2-$ moieties of the Aebersold et al linker). For the “post-translationally modified amino acid side chain” of instant claim 5, see Aebersold et al, col. 6, lines 46-65. For the “plurality of PMT reagents” of instant claim 8, see col. 5, lines 39-42. The “amino acid reactive moiety” which is reactive with the guanidinium group (which itself contains an amine function) of arginine (instant claims 7 and 11) is described by Aebersold et al at col. 10, lines 46-52.

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8) Claims 1-4, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Morgan, Jr. et al (U.S. 5,840,712).


The "reagent" of instant claim 1 which requires *solely* "an amino reactive moiety" and a "differential label" composed of "non-isotopic chemical substituent(s)" is readable on and therefore anticipated by the heterobifunctional linkers of Morgan, Jr. et al (see TABLE 2). For example the sulfo-SMCC of col. 15, third structure, of TABLE 1 of Morgan, Jr. et al contains the thiol reactive maleimide moiety ("an amino acid reactive moiety that selectively reacts with certain protein functional groups" {instant claim 1}) and a sulfosuccinimidyl group ("one non-isotopic chemical substituent" {instant claim 1}). The SMPB reagent of TABLE 2 (last structure of col. 15 of Morgan, Jr. et al) contains an amine reactive N-hydroxysuccinimidyl ester ("an amino acid reactive moiety that selectively reacts with certain protein functional groups") and a maleimide group ("one non-isotopic chemical substituent" {instant claim 1}).

9) An inquiry of a general nature which is **not related to the prosecution on the merits** should be directed to Technology Center 1600 telephone number (571) 272-1600. The general fax number for the USPTO is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823.

June 24, 2004


Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641